



LAP15 Rec'd PCT/PTO 26 MAY 2006  
PCT

PATENT  
ATTORNEY'S DOCKET NO.: NBG-109

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Aldo Salimbeni et al.  
Serial No.: Unassigned National Stage of  
PCT/EP03/13696  
Filed: June 6, 2005  
For: PROCESS FOR THE PREPARATION OF  
BYCYCLIC PEPTIDE COMPOUNDS  
Examiner: Not Assigned  
Art Unit: Not Assigned  
Confir. No.: 7958

---

CERTIFICATE OF MAILING

*I hereby certify that the following correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313—1450 on May 23, 2006.*

  
Mark D. Lorusso

---

Mail Stop: PCT  
Commissioner for Patents  
PO BOX 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 C.F.R. §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the applicants request consideration of this information disclosure statement.

**Compliance with 37 C.F.R. §1.97**

This information disclosure statement has been filed before the mailing of a first office action on the merits. No fee or certification is required.

**Information Cited**

The applicants hereby make of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the relative importance of the references.

**Remarks**

Pursuant to 37 C.F.R. § 1.98(a)(2)(i), copies of non-U.S. patent references are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). A copy of an International Search Report in which the references are identified and their relevance highlighted is also enclosed. It is respectfully requested that:

- The examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- The enclosed form PTO-1449 be signed by the examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- The citations for the information be printed on any patent which issues from this application.

By submitting this information disclosure statement, the applicants make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

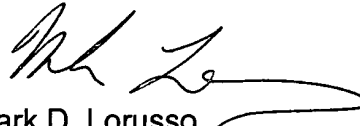
By submitting this information disclosure statement, the applicants make no representation that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this information disclosure statement, the applicants make no representation that the information cited in the statement is, or is considered to be, in

fact, prior art as defined by 35 U.S.C. §102.

It is understood by applicants that the foregoing information will be considered and, to the extent deemed appropriate by the examiner, will be reflected in the examiner's communication.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark D. Lorusso', with a long, sweeping horizontal line extending to the right.

Mark D. Lorusso  
Reg. No. 41,955  
Lorusso & Associates  
3 Pinecrest Terrace  
Portsmouth, NH 03801  
Tel: (603) 427-0070  
Attorneys for Applicants

Docket No.: NBG-109

Date: May 23, 2006

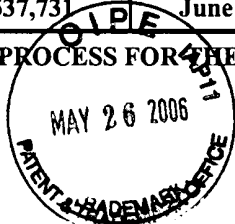
**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
NBG-109

In Re Application of: Aldo Salimbeni et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/537,731	June 6, 2005	Unassigned	48388	Unassigned	7958

Title: **PROCESS FOR THE PREPARATION OF BYCYCLIC PEPTIDE COMPOUNDS**



**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 12-2147 as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fa

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Typed or Printed Name of Person Signing Certificate

**\*This certificate may only be used if paying by deposit account.**

\_\_\_\_\_  
Signature

**Certificate of Mailing by First Class Mail**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

May 23, 2006

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature of Person Mailing Correspondence

Mark D. Lorusso

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Certificate

Dated: May 23, 2006

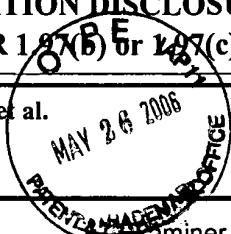
Mark D. Lorusso  
Reg. No. 41,955  
LORUSSO & ASSOCIATES  
3 Pinecrest Terrace  
Portsmouth, NH 03801  
Tel.: 603-427-0070  
Fax: 603-427-5530  
Email: mlorusso@lilplaw.com

CC:

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
NBG-109

In Re Application Of: Aldo Salimbeni et al.



Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/537,731	June 6, 2005	Unassigned	48388	Unassigned	7958

Title: **PROCESS FOR THE PREPARATION OF BYCYCLIC PEPTIDE COMPOUNDS**

Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

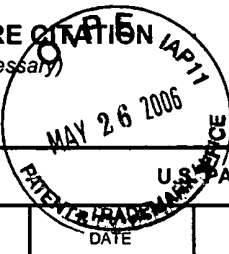
2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. <b>NBG-109</b>		APPLICATION NO. <b>10/537,731</b>	
				APPLICANT(S) <b>Aldo SALIMBENI et al.</b>			
				FILING DATE <b>6/6/2005</b>		GROUP ART UNIT <b>N/A</b>	



U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	

U.S. PATENT APPLICATION PUBLICATIONS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		WO 96/28467 A	9/19/1996	WIPO-ITALY	C07K	7/22	✓	

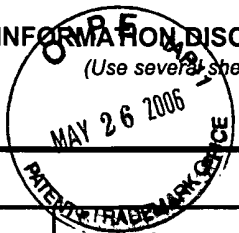
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
		<b>*WEISSHOFF H ET AL:</b> "Structure determination and by-product profile of the NK2 receptor antagonist nepadutant, a bicyclic glycopeptid"; FEBS LETTERS, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 491, no. 3; 3/2/2001, pgs 299-304. <b>*ANISFELD S T ET AL:</b> "A CONVERGENT APPROACH TO THE CHEMICAL SYNTHESIS OF ASPARAGINE-LINKED GLYCOPEPTIDES" JOURNAL OF ORGANIC CHEMISTRY, vol. 55, no. 21, 1990, pgs 5560-5562, XP002288954, ISSN: 0022-3263. <b>*OFFER J ET AL:</b> "ON-RESIN SOLID-PHASE SYNTHESIS OF ASPARAGINE N-LINKED GLYCOPEPTIDES:USE OF N-(2-ACETOXY-4-METHOXYBENZYL)(ACHMB) ASPARTYL AMIDE-BOND PROTECTION TO PREVENT UNWANTED ASPARTIMIDE FORMATION" JOURNAL OF THE CHEMICAL SOCIETY, PERKIN TRANSACTIONS 1, CHEMICAL SOCIETY. LETCHWORTH, GB, vol. 2, 1996, pgs. 175-182, XP002055030; ISSN: 0300-922X.

EXAMINER	DATE CONSIDERED
----------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# **INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)



ATTY DOCKET NO. <b>NBG-109</b>		APPLICATION NO. <b>10/537,731</b>	
Aldo SALIMBENI et al.			
FILING <b>6/6/2005</b>		GROUP ART <b>N/A</b>	

## **U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## **U.S. PATENT APPLICATION PUBLICATIONS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## **FOREIGN PATENT DOCUMENTS**

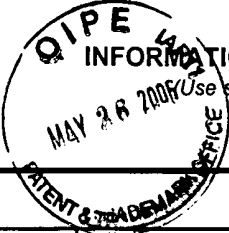
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

## **OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

			*TUCHALSKI, GIBERT ET AL: "Large scale synthesis of biologically active bicyclic hexapeptides"; PEPTIDES 1996, PROCEEDINGS OF THE EUROPEAN PEPTIDE SYMPOSIUM, 24TH, EDINBURGH, SEPT.8-13, 1996 (1998), MEETING DATE 1996, 845-846. EDITOR(S) RAMAGE, ROBERT; EPTON, ROGER. PUBLISHER: MAYFLOWER SCIENTIFIC, KINGSWINFORM, UK., 1998; XP009028177.
			*AKAJI, K ET AL: "Synthesis of MEN11420, a glycosylated bicyclic peptide using a chloroimidazolinium coupling reagent", TETRAHEDRON, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 57, no. 9, 2/25/2001, pgs 1749-1755, XP004317634; ISSN: 0040-4020.

EXAMINER	DATE CONSIDERED
----------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

 <p><b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)</p>				ATTY DOCKET NO. <b>NBG-109</b>		APPLICATION NO. <b>10/537,731</b>		
				Aldo SALIMBENI et al.				
				FILING <b>6/6/2005</b>		GROUP ART <b>N/A</b>		
<b>U.S. PATENT DOCUMENTS</b>								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<b>FOREIGN PATENT DOCUMENTS</b>								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
			<p>*CACIAGLI V ET AL: "LARGE SCALE PRODUCTION OF PEPTIDES USING THE SOLID-PHASE CONTINUOUS FLOW METHOD. PREPARATIVE SYNTHESIS OF THE NOVEL TACHYKININ ANTAGONIST MEN 10327" JOURNAL OF PEPTIDE SCIENCE, JOHN WILEY AND SONS LTD, GB, vol. 3, no. 3, 05/1997, pgs 224-230, XP009028229; ISSN: 1075-2617.</p> <p>*INTERNATIONAL SEARCH REPORT; 7/12/2004; 7 pgs.; T.VOGT.</p>					
			<p>*DAVIS BENJAMIN G: "Synthesis of glycoproteins." CHEMICAL REVIEWS, FEB 2002, vol. 102, no. 2, February 2002, pages 579-601, XP002288955, ISSN: 0009-2665</p>					
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>				
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>								